



August 29, 2023

SUBMITTED ELECTRONICALLY

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: ITEM Coalition Comment Letter on the CY 2024 Home Health Payment Rule and Proposed Definition of an Orthotic Brace (CMS-1780-P)

Dear Administrator Brooks-LaSure:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition appreciate the opportunity to provide comments to the Centers for Medicare and Medicaid Services (“CMS”) in response to the CY 2024 Home Health Prospective Payment System Proposed Rule (“Proposed Rule”)¹. Our comments are focused solely on the proposed definition of a “Brace” under the Medicare orthotic benefit and CMS’s proposal to define as covered Medicare benefits orthoses with powered features designed to assist with traditional bracing functions.

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including limb loss and limb difference, multiple sclerosis, spinal cord injury, brain injury, stroke, paralysis, cerebral palsy, spina bifida, hearing, speech, and visual impairments, myositis, and other life-altering conditions.

¹ Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements, 88 Fed. Reg. 43,654 (July 10, 2023), <https://www.federalregister.gov/documents/2023/07/10/2023-14044/medicare-program-calendar-year-cy-2024-home-health-hh-prospective-payment-system-rate-update-hh>.

Proposed Definition of a “Brace” under the Medicare Orthotic Benefit

Orthotic braces are critically important devices used by individuals with limb difference to protect, support, or re-align body segments such as the trunk, spine, or extremities. The ITEM Coalition believes that the Proposed Rule represents a positive step forward in the right direction towards greater access to orthotic care for Medicare beneficiaries with limb differences. The Proposed Rule would elevate the definition of an orthotic brace from the Medicare Benefit Policy Manual (“MBPM”) to the regulations at 42 C.F.R. § 410.2. This codification would strengthen the current definition of a brace (orthosis) under the Medicare benefit and make it more reliable and durable from one Administration to another.

Currently, the term “brace” is not defined in the Medicare statute or in its implementing regulations. Instead, the MBPM defines braces as “rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.” Under the proposal, CMS would codify this definition in regulation, which would help ensure that patients of all ages have access to technology that best meets their functional needs.

Elevating the orthotic definition to regulation will help settle orthotic coverage; however, we do wish to note that the *non-binding* preamble language in the proposed rule describing the proposed regulatory change uses outdated and fairly simplistic concepts of orthotic treatment. The ITEM Coalition believes that this preamble language oversimplifies the design and function of modern orthotic braces and, in doing so, could be a reflection of how CMS continues to view orthotics. From a functional standpoint, braces are used to enhance the ability to effectively utilize affected upper and lower limbs to better perform activities of daily living. In contemporary practice, orthoses are externally applied devices used to support body segments or joints which are weakened, unstable or mal-aligned, for the purpose of enhancing function and individual independence. While the ITEM Coalition supports the codification in regulation of the existing definition of orthotic braces, we strongly urge CMS to interpret the orthotic benefit through contemporary orthotic clinical practice when making coding, coverage and payment decisions in the future.

Proposal to Include Powered Features in the Medicare Definition of an Orthotic “Brace”

The ITEM Coalition is very pleased that CMS is also proposing in this Proposed Rule for devices with powered features designed to assist with traditional bracing functions to be considered braces for Medicare coverage purposes. This CMS proposal rightfully recognizes coverage of powered orthotic technologies that have tremendous potential in the future to meet patient’s needs. For several years, CMS has signaled an interest in interpreting the orthotic definition narrowly, and not accepting the concept of covering orthoses which include powered features to support the function of more traditional orthoses. We are grateful that CMS has determined, through this proposed rule, that powered orthoses are, in fact, eligible for coverage under the Medicare program. As such, the ITEM Coalition encourages CMS to finalize this regulation as originally proposed.

CMS clarifies in the Proposed Rule that powered features designed to assist with traditional bracing functions are considered orthoses under the Medicare benefit. CMS specifically states in

the Proposed Rule that three Healthcare Common Procedure Coding System (“HCPCS”) codes are now considered orthoses, including:

- **HCPCS Code L8701** (Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated);
- **HCPCS Code L8702** (Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated); and
- **HCPCS Code K1007** (Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors)

HCPCS Code L8701 and HCPCS Code L8702 are both upper extremity orthoses with powered joints that are myoelectrically controlled by the patient’s muscle signal and are utilized to assist individuals with impaired upper limb function to perform activities of daily living. HCPCS Code K1007 is an exoskeleton device that uses motion sensors to help beneficiaries with paralysis stand and ambulate with the assistance of forearm crutches. While the ITEM Coalition does not address specific brand names, we remain highly supportive of covering these categories of innovative technologies for Medicare beneficiaries with functional impairments.

Medicare beneficiaries will gain the much-needed access to this innovative category of orthoses for years to come. We applaud and greatly appreciate the agency’s acknowledgement in this Proposed Rule that technology has evolved to include newer technology devices with power features designed to assist with traditional bracing functions. In moving forward, we encourage CMS to ensure that candidates for powered orthoses are selected carefully to prevent waste and abuse, with appropriate training for the patient as well as orthotic and other qualified clinicians.

We appreciate your consideration of these comments. Should you have any further questions regarding this letter, please contact the ITEM Coalition Co-Coordinator at Peter.Thomas@PowersLaw.com or Michael.Barnett@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready
ACCSES
American Academy of Physical Medicine and Rehabilitation
American Association for Homecare
American Association on Health and Disability

American Music Therapy Association
American Therapeutic Recreation Association
Amputee Coalition*
Association of Rehabilitation Nurses
Autistic Women & Nonbinary Network
Christopher and Dana Reeve Foundation*
Clinician Task Force
Council of State Administrators of Vocational Rehabilitation (CSAVR)
Institute for Matching Person and Technology
Lakeshore Foundation
National Association for Home Care & Hospice
National Disability Rights Network
Paralyzed Veterans of America*
Spina Bifida Association*
Support Sight Foundation
United Cerebral Palsy
United Spinal Association*

Indicates ITEM Coalition Steering Committee Member*